510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Trabecular Metal Femoral Cone Augments

Submitter Name And Address:

Zimmer Trabecular Metal Technology, Inc.

80 Commerce Drive

Allendale, New Jersey 07401-1600

Contact Person:

Marci Halevi

Phone Number:

(201) 818-1800

Fax Number:

(973) 829-0825

Date Prepared:

June 30, 2005

Device Trade Name:

Trabecular Metal Femoral Cone Augments

Device Common Name:

Knee System Augments

Classification Number

21 CFR § 888.3560 Prosthesis, Knee

and Name:

Device Description:

The Trabecular Metal Femoral Cone Augments are to be used in conjunction with Zimmer Inc.'s LCCK and Rotating Hinge Knee femoral components. The subject devices are used to address distal femoral cavitary defects encountered when implanting either of these two systems. The design of the augment interface inversely corresponds to the design of an LCCK or Rotating Hinge Knee femoral component. augment has a rectangular, tapered shape. The opposing sides of the rectangle are longer than the center allowing the sides of the augment to fit into the condyles of the femoral component and the center of the augment to fit over the "box" of the femoral The center of the augment is hollow to allow passage of the stem through the center of the cone and into the femoral canal. The augments are fixed to the femoral component with bone cement. The Trabecular Metal Femoral Cone Augments are for cemented use along the bone in the USA, and for cementless or cemented use along the bone outside the USA.

510(k) Summary (Continued)

Indications for Use:

The Trabecular Metal Femoral Cone Augments are indicated for use in the reconstruction of bony defects in knee reconstruction due to severe degeneration, trauma, or other pathology of the knee joint, and in the revision or salvage of failed, previously reconstructed knee procedures and implants. The Trabecular Metal Tibial Cone Augments are for cemented use only in the USA, and for cementless

or cemented use outside the USA.

Device Technological Characteristics and Comparison to **Predicate Device:**

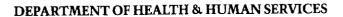
A comparison of device technological characteristics and properties demonstrates that the device is substantial equivalent to the cited predicate devices.

Performance Data:

Testing of the subject devices were not performed. Previous testing of Trabecular Metal and Trabecular Metal determination of substantial support а equivalence.

Conclusion:

The Trabecular Metal Femoral Cone Augments are equivalent to the predicate devices substantially (K040630) identified in this premarket notification.





JUL 2 8 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Ms. Marci Halevi Manager of Regulatory Affairs Zimmer Trabecular Metal Technology, Inc. 80 Commerce Drive Allendale, New Jersey 07401-1600

Re: K051756

Trade/Device Name: Trabecular Metal Femoral Cone Augments

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer

semi-constrained cemented prosthesis

Regulatory Class: II Product Code: JWH Dated: June 28, 2005 Received: June 29, 2005

Dear Ms. Halevi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson Acting Director

Division of General, Restorative and Neurological Devices
Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

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Indications for Use

indications for Osc
510(k) Number (if known):
Device Name:
Indications for Use:
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Prescription Use AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
(Posted November 13, 2003) (Division Sign-Off) Division of General, Restorative and Neurological Devices (**Posted November 13, 2003)